

| <b>Notice of Allowability</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|-------------------------------|--------------------------|---------------------|--|
|                               | 10/630,604               | AOKI ET AL.         |  |
|                               | Examiner<br>Chih-Min Kam | Art Unit<br>1656    |  |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 9/8/06.
2.  The allowed claim(s) is/are 1,4,5,9,12 and 29-36.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 4, 5, 9, 12, 13 and 29-36 are pending.

Applicants' response and Declaration of Stephen Donovan filed September 8, 2006 is acknowledged. Applicants' response and Declaration of Stephen Donovan have been fully considered. Therefore, claims 1, 4, 5, 9, 12, 13 and 29-36 are examined.

### **Withdrawn Claim Rejections - 35 USC § 103**

2. The previous rejection of claims 1, 4, 5, 12, 13 and 29, under 35 U.S.C. 103(a) as being unpatentable over Coe *et al.* (US 2001/0036943), is withdrawn in view of applicants' response at page 2 of the response and Declaration of Stephen Donovan filed September 8, 2006.

### **Withdrawn Claim Rejections-Obviousness Type Double Patenting**

3. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 29-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 31-32 of co-pending application 10/630,206 is withdrawn in view of applicants' submission of a terminal disclaimer, and applicants' response at page 3 in the response filed September 8, 2006.

### ***Examiner's Amendment***

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Claude Nassif on November 16, 2006.

**Examiner's Amendment to the Specification:**

Please replace the paragraph after the subtitle "CROSS REFERENCE" of the specification in the preliminary amendment filed July 29, 2003 with the following paragraph:

This application is a continuation of application serial number 10/199,222, filed July 18, 2002, now U.S. patent no. 6,869,610, which is a continuation of serial number 09/550,371, filed April 14, 2000, now U.S. patent no. 6,464,986 B1, the entire contents of which prior application and patent are incorporated herein by reference in their entireties.

**Examiner's Amendment to the Claims:**

Cancel claim 13.

Claims 12 and 32 have been amended as follows:

12. (Currently amended) A method for alleviating a burn pain, the method comprising the step of peripheral administration of an effective amount of a botulinum toxin type A to a human patient, thereby alleviating the burn pain.

32. (Currently amended) The method of claim 31, wherein the botulinum toxin is a botulinum toxin type A.

**The following is an Examiner's Statement of Reasons for Allowance:** The following references appear to be the closest art to the claimed invention. Aoki et al. (U. S. Patent 6,113,915) teach a method for treating pain, comprising intraspinal administration of a therapeutically effective amount of a botulinum toxin to a mammal. However, the patent of Aoki et al. does not teach a method of treating a burn pain, comprising the step of peripheral or local administration of a botulinum toxin as claimed in the instant application. Coe et al. (US 2001/0036943, filed on 12/18/00 and published on 11/1/01) teach a method of treating a disorder or condition in which pain predominates including burn pain in a mammal by administering a pain attenuating effective amount of a pharmaceutical composition comprising a nicotine receptor partial agonist, an analgesic agent and a pharmaceutically acceptable carrier, where a botulinum toxin can be used as an analgesic agent, and the composition can be administered locally including intramuscular administration. However, the reference by Coe et al. has an

effective filing date and publication date later than the priority date of instant application (4/14/00). Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

November 16, 2006